DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avitall (5,454,370) in view of Edwards et al. (5,423,808).

Regarding claim 9, Avitall discloses a radiofrequency electric current ablation catheter (col. 1, lines 11-12) comprising: a tip electrode (Fig. 5); a catheter shaft (14); and a portion for operation at a proximal end (70), wherein the tip electrode has a shape formed by connecting three or more spherical or approximately spherical surfaces having centers on a same straight line to each other with a curved surface (Fig. 5 shows approximately spherical surfaces) but fails to disclose means for detecting a temperature of the tip electrode.

However, Edwards et al. teach temperature sensing means 84 includes a small bead thermistor 94.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a thermistor as taught by Edwards et al., since Edwards et al. state that cardiac ablation especially requires the ability to precisely monitor and control the emission of energy from the ablation electrode (col. 1, lines 41-43), where monitoring and control of tissue impedance and tissue temperature, either separately or in combination, set safe physiological limits in terms of lesion size and detection of coagulation and also provide information regarding orientation of the ablation electrode (col. 12, lines 35-41).

Regarding claim 10, Avitall discloses the ablation catheter according to Claim 9, wherein at least one of the three or more spherical or approximately spherical surfaces is a surface selected from a spherical surface, a surface of an ellipsoid of revolution having an axis on a central axis of the catheter, an egg-shaped surface having an axis

on a central axis of the catheter and a hemispherical surface having an axis on a central axis of the catheter (Fig. 5).

Regarding claims 11 and 12, Avitall discloses the tip electrode has a length of 0.5 to 15 mm and a maximum outer diameter of 0.5 to 3 mm (typical diameter of the working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and 2 mm electrode, col. 4, lines 11-12).

Regarding claims 13 and 14, Avitall discloses when an average diameter of adjacent two spherical or approximately spherical surfaces is represented by D and a distance between centers of the adjacent two spherical or approximately spherical surfaces is represented by d, d/D is 0.1 to 2 with respect to entire combinations of adjacent two spherical or approximately spherical surfaces (typical diameter of the working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and the distance between electrodes is typically 0.5 mm or less, col. 4, lines 11-12).

Regarding claims 15 and 16, Avitall discloses ablation when an average diameter of adjacent two spherical or approximately spherical surfaces is represented by D and a distance between centers of the adjacent two spherical or approximately spherical surfaces is represented by d, d/D is 0.5 to 1.25 with respect to entire combinations of adjacent two spherical or approximately spherical surfaces (typical diameter of the working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and the distance between electrodes is typically 0.5 mm or less, col. 4, lines 11-12).

Regarding claims 17 and 18, Avitall discloses the tip electrode has a length of 1 to 12 mm and a maximum outer diameter of 1 to 2.7 mm (typical diameter of the

working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and 2 mm electrode, col. 4, lines 11-12).

Regarding claims 19 and 20, Avitall discloses when an average diameter of adjacent two spherical or approximately spherical surfaces is represented by D and a distance between centers of the adjacent two spherical or approximately spherical surfaces is represented by d, d/D is 0.1 to 2 with respect to entire combinations of adjacent two spherical or approximately spherical surfaces (typical diameter of the working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and the distance between electrodes is typically 0.5 mm or less, col. 4, lines 11-12).

Regarding claims 21 and 22, Avitall discloses when an average diameter of adjacent two spherical or approximately spherical surfaces is represented by D and a distance between centers of the adjacent two spherical or approximately spherical surfaces is represented by d, d/D is 0.5 to 1.25 with respect to entire combinations of adjacent two spherical or approximately spherical surfaces (typical diameter of the working catheter area is approximately 5 F to 10 F, col. 2, lines 65-67; and the distance between electrodes is typically 0.5 mm or less, col. 4, lines 11-12).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5275162 A; US 5313943 A; US 5327905 A; US 5354297 A; US 5374285 A; US 5396887 A; US 5400783 A; US 5642736 A; US 5688266 A; US

5722975 A; US 5743903 A; US 5779669 A; US 6023638 A; US 6165172 A; US 6212426 B1; US 20010041888 A1; and US 20020007181 A1.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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